[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN: # 3150-AG81

Notification Requirement

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend certain provisions of its regulations that govern the medical use of byproduct material. The proposed rule would require a licensee to notify the NRC and an identified exposed individual shortly after the licensee becomes aware that the individual received or is estimated to have received a dose exceeding 50 millisievert (mSv) [5 rem] from a released patient who had been administered radioactive material. In addition, the proposed rule would require a licensee to submit a written report to the NRC within 15 days after discovery of the event and to provide a copy of the report to the identified exposed individual. NRC is specifically soliciting comments on issues raised by the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

DATES: The comment period expires **[insert 75 days after publication in the Federal Register].** Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website (http://ruleforum.llnl.gov) . This site provides the capability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415-5905, or e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking website.

Documents created or received at the NRC after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to PDR@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Betty Ann Torres, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 [telephone, (301) 415-0191, email: BAT@nrc.gov .]

SUPPLEMENTARY INFORMATION:

Background

The NRC regulates the use of byproduct material in medicine for diagnosis and treatment of disease and research programs. Each year in the United States, radioactive pharmaceuticals or radioactive implants are administered to several million patients. These patients can expose other individuals to radiation until the radioactive material has decayed or has been excreted. The doses received from different radionuclides can vary greatly even though the quantities of the radionuclides may be equal. For this reason, on June 15, 1994 (59 FR 30724), the NRC proposed a revision of the regulations at 10 CFR 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material,” to make the criteria for patient release dose-based, rather than activity-based. A dose-based criteria provides a uniform measure of protection to exposed individuals. The final rule was published January 29, 1997 (62 FR 4120), and allows individuals who have received byproduct material to be released “if the total effective dose equivalent to any individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).”

Patient release is governed by 10 CFR 35.75, because the current regulations, 10 CFR 20.1002, 20.1003, and 20.1301(a)(1), provide that the dose limits in Part 20 do not apply to: (1) doses from background radiation; (2) exposure of patients to radiation for the purpose of medical diagnosis or therapy; (3) exposure from individuals administered radioactive material and released in accordance with § 35.75; or (4) exposure from voluntary participation in medical research programs.

Discussion

In 1997, the NRC initiated a rulemaking process that would result in a complete revision of 10 CFR Part 35, “Medical Uses of Byproduct Material.” The Commission supported continuation of the medical use program with decreased oversight of low-risk activities and continued emphasis on high-risk activities. The primary purpose of the revision of 10 CFR Part 35 was to restructure the regulation into a more risk-informed and more performance-based regulation.

A final rule that revised 10 CFR Part 35 was published on April 24, 2002, and becomes effective October 24, 2002. During consideration of this rule, the Commission noted that licensees were not required to notify the NRC if they learned that an individual received a dose in excess of the dose specified in 10 CFR 35.75 from a patient released under that provision. The Commission also noted licensees were not required to notify the exposed individual of the exposure. The Statement of Considerations for the January 29, 1997, final rule (62 FR 4120) revising 10 CFR 35.75 did not discuss whether reporting was required if the licensee failed to comply with 10 CFR 35.75 and an individual received a dose in excess of 5 mSv (0.5 rem), or complied with 10 CFR 35.75, but learned that an individual exposed to the released individual, nevertheless, received a dose in excess of 5 mSv (0.5 rem). As a result, the NRC subsequently decided to address the issue of notification and reporting in these situations in a separate rulemaking.

This proposed rule would require a licensee to notify the NRC and an identified exposed individual no later than the next calendar day or 24 hours, respectively, after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a released individual who contains unsealed byproduct material or implants containing byproduct material. The proposed rule also would require a licensee to submit a written report to the NRC within 15 days after discovery of the event, and to provide a copy of the report to the identified exposed individual. This rulemaking would encompass a patient release

where a licensee fails to comply with § 35.75, as well as a release that was in compliance. The Commission believes that the most likely basis for reporting will be instances in which the licensee either:

(1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate; or

(2) learns, through voluntary means, that the patient did not follow the physician's instructions.

If the patient did not follow the physician's instructions, please note that the Commission is not modifying its previous position of January 29, 1997 (62 FR 4120), that:

(1) The NRC does not intend to enforce a patient's compliance with the licensee's instructions; and

(2) The licensee is not responsible for ensuring compliance by patients once they are released from the licensee's facility.

Although this rule would result in a minimal increase in regulatory burden, the Commission believes that the information obtained in accordance with the proposed notification and reporting requirement is needed. There would be no change to the safety standards and dose limits currently in place. However, reporting exposures greater than 50 mSv (5rem) would provide information that can be used to determine if the assumptions used for patient release remain valid. In addition, such reports can illuminate whether any regulatory modifications are needed in this area in order to maintain public health and safety. With this information available to allow feedback on the outcomes achieved under the current regulations, the Commission believes that NRC's regulatory program would be strengthened.

Coordination with the Advisory Committee on the Medical Uses of Isotopes

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of byproduct material and radiation from byproduct material. The NRC discussed this rulemaking with the ACMUI at public meetings held on November 8-9, 2000 and April 18, 2001. In November 2000, the ACMUI recommended that NRC limit the reporting requirement to only those instances where the licensee made an error in the release of the patient, or errors made in delivery of instructions to the patient. In April 2001, the ACMUI reaffirmed its previous position. Members of the ACMUI also expressed concern about implementation, inspection, and enforcement of the rule. The transcripts of both meetings are available for review on the NRC website at http://www.nrc.gov/NRC/ADAMS/index.html. The ADAMS document accession numbers are ML003772075 for the November 2000, ACMUI meeting transcript and ML011380698 for the April 2001, ACMUI meeting transcript. During the April discussion of this issue, ACMUI indicated the following concerns. NRC is soliciting public comments on these issues as they relate to the proposed rule.

- Licensees may be reluctant to release patients under § 35.75 because of repercussions associated with the reporting requirement, such as, negative press and loss of public confidence. This will result in more expensive care for these patients.
- Licensees should be granted anonymity when reporting the event and not be held responsible for patients who disregard instructions.
- Licensees may have to report based on information that may be difficult to verify. For example, an individual could call the licensee with a concern or a question about the patient's behavior.

- Patients and licensees could be subject to intrusive investigations with possible loss of patient confidentiality.
- Dose reconstructions would be based on numerous variables with significant ranges of uncertainties.
- Low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditure.
- NRC and licensee effort should focus on compliance with § 35.75.

Consistency with the 2000 Medical Policy Statement

The proposed rule is consistent with the NRC's revised Medical Policy Statement (MPS) which became effective August 3, 2000 (65 FR 47654). The overall goals of the regulatory program concerning the medical use of byproduct material are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be more risk-informed and more performance-based.

The first statement of the MPS is "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with this statement because the purpose of the rule is to further the protection of the health and safety of individuals exposed to patients who have been administered radioactive material by providing a feedback mechanism for significant deviations from the expected outcome of releasing a patient.

The proposed rule is also consistent with the second statement, "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of

workers and the general public," because the regulatory purpose of the reporting requirement is focused on a significant deviation from a dose threshold as opposed to medical judgment.

The third statement, "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's direction," is not relevant to this proposed rule because the rule would further the radiation safety of individuals exposed to the patients, rather than the radiation safety of the patients themselves.

The fourth statement of the MPS is "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." This statement is not relevant to the proposed rule because there are no industry and professional standards to be considered in developing this notification and reporting requirement.

Discussion of Proposed Amendments by Section

Table of Contents

The Table of Contents is revised to reflect that a new section is being added to the rule.

§ 35.8, "Information collection requirements: OMB approval."

This section is revised to add § 37.3075 to the list of approved sections with information collection requirements.

§ 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material.”

This section is revised to add a statement that refers to the notifications required by § 35.3075.

§ 35.3075, “Report and notification of a dose greater than 50 mSv (5 rem) to an individual from a patient released under § 35.75.”

This new section would be added to 10 CFR Part 35 to require that a licensee notify the NRC and the affected individual no later than the next calendar day or 24 hours, respectively, after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. This rulemaking includes instances where the licensee: (1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate; or (2) learns, through voluntary means, that the patient did not follow the physician’s instructions. In addition, the revised rule would require the licensee to submit a written report to the NRC within 15 days after discovery of the event and to provide the exposed individual with a copy of that report.

Agreement State Compatibility

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this proposed rule would be a matter of compatibility between the NRC and Agreement States, thereby providing consistency among the Agreement State and NRC requirements. A Compatibility “C” designation means that the essential objectives of an NRC program element should be adopted by Agreement States to avoid conflicts, duplication, or gaps in the regulation of agreement material on a nationwide basis. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met. A Compatibility Category “D” designation means an NRC program element which does not need to be adopted by Agreement States for purposes of compatibility.

The proposed revision to 10 CFR 35.8 would be classified as Compatibility Category “D.” The proposed revision to 10 CFR 35.75 would be classified as Compatibility Category “C”. The proposed revision of 10 CFR Part 35 in Subpart M, “Reports,” adding a notification and reporting requirement under a new 10 CFR 35.3075 also would be classified as Compatibility Category “C.”

Plain Language

The Presidential memorandum dated June 1, 1998, entitled “Plain Language in Government Writing” directed that the Government’s writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading “ADDRESSES” above.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104-113), requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with the applicable law or otherwise impractical. In this proposed rule, the NRC would revise 10 CFR Part 35 to add 10 CFR 35.3075 to require notification and reporting when a licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. This action does not constitute the establishment of a standard that establishes generally-applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22 (c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for this information collection is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The

U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection contained in the proposed rule and on the following issues:

- Is the proposed information collection necessary for the proper performance of the functions of NRC, including whether the information will have practical utility?
- Is the estimate of burden accurate?
- Is there a way to enhance the quality, utility, and clarity of the information to be collected?
- How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by internet electronic mail at BJS1@nrc.gov ; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010), Office of Management and Budget (OMB), Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by **[insert 30 days after publication in the Federal Register]**. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

NRC's Medical Use Program includes the regulation of the use of byproduct material in medical diagnosis, therapy, and research. There are approximately 1,655 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. There are approximately 4,138 State licenses in Agreement States authorizing the medical use of byproduct material. The Commission is proposing a revision to 10 CFR Part 35 that would require a licensee to notify and report to the NRC if an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. In addition, the licensee must also notify and provide a written report to the identified exposed individual.

The options are either:

(1) Do not require the licensee to notify and report to the NRC and an identified exposed individual when an individual receives an exposure greater than 50 mSv (5 rem) from a patient released under 10 CFR 35.75; or

(2) Require the licensee to notify and report to the NRC and an identified exposed individual in such an event.

With no rulemaking action, costs to licensees are not affected. With a rulemaking action, minimal cost increases are anticipated from the notification and reporting requirements proposed by this rulemaking. Because dose received by an individual from a patient released under 10 CFR 35.75 is not currently reportable, no database exists for determining the frequency of this type of event. The Nuclear Materials Events Database (NMED) (1995 to present) identified 15 incidents that resulted in overexposures to the public, but there were no reports of overexposures to members of the public as a result of being exposed to patients released under 10 CFR 35.75. However, for the purpose of this regulatory analysis, the assumption is that NRC will receive one

notification and report per year from the entire medical community, not per licensee. Listed below is an estimate of the increased cost anticipated from the notification and submission of a written report to the NRC and identified exposed individual when the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75.

Assumptions:		
Total annual reports from all licensees:		1
Total phone reporting time (hours)		0.5
Technical staff hourly rate:		$ 143
Total Annual Cost Increase for Licensees:		$ 72

Assumptions:		
Total annual license events requiring reporting under § 35.75:		1
Total report preparation time (hours)	5	
Technical staff hourly rate:		$ 143
Total Annual Cost Increase for Licensees:		$ 715

From this analysis, the estimated total annual increased cost to the medical community is anticipated to be $787 for a licensee who notifies and submits a written report to the NRC and identified exposed individual when the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial

number of small entities. This proposed rule adds a reporting requirement for an incident which is estimated to occur infrequently. Therefore, the economic impact on small entities is negligible.

Backfit Analysis

The NRC has determined that the backfit rules (10 CFR 50.109, 72.62, or 76.76) do not apply to this proposed rule because these amendments do not involve any provision that would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

List of Subjects

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 35.

PART 35 — MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat.1242, as amended (42 U.S.C. 5841).

2. In the Table of Contents under Subpart M, Reports, the following heading is added:

* * * * *

35.3075 Report and notification of dose to an individual from a released patient.

* * * * *

3. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26. 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 36.3067, and 35.3075.

* * * * *

4. In § 35.75, paragraph (e) is added to read as follows:

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

* * * * *

(e) The licensee shall notify the NRC and file a report, if required, in accordance with § 35.3075.

5. Section 35.3075 is added under Subpart M to read as follows:

§ 35.3075 Report and notification of dose to an individual from a released patient.

(a) A licensee shall report any dose greater than 50 mSv (5 rem) total effective dose equivalent that an individual receives from a patient released under § 35.75.

(b) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after the licensee becomes aware of an event that requires a report in paragraph (a) in this section.

(c) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after the licensee becomes aware of a dose to an individual that requires a report in paragraph (a) in this section. The individual(s) receiving a dose described in paragraph (a) is referred to as identified exposed individual(s).

(1) The written report must include —

(i) The licensee's name;

(ii) The estimated dose(s) to the identified exposed individual(s);

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) What actions, if any, have been taken or are planned to prevent recurrence;

(vi) Certification that the licensee notified the identified exposed individual(s).

(2) The report shall not contain the names of the identified exposed individual(s), the individual released under § 35.75, or any other information that could lead to the identification of the exposed individual(s) or the individual released under § 35.75.

(d) The licensee shall provide notification of the event to the identified exposed individual(s) no later than 24 hours after the licensee becomes aware of an event that would require reporting under paragraph (a) of this section.

(e) The licensee shall provide the identified exposed individual(s) with a copy of the report submitted to the Commission.

Dated at Rockville, Maryland, this _____ day of _____, 2002.

For the Nuclear Regulatory Commission.

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Annette L. Vietti-Cook,
Secretary of the Commission.